THE PROPRIETARY ASSOCIATION

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Food and Drug Administration
Department of Health and Human
Services
Room 4-62
5600 Fishers Lane
Rockville, Maryland 20857

Citizen Petition

The undersigned submits this petition under Section 201 of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to reopen that portion of the administrative record of the OTC Drug Review which concerns nasal decongestants, covered under the Proposed Monograph for OTC Cold, Cough, Allergy, Bronchodilator and Antiasthmatic Products, 41 Fed. Reg. 38,312, 38,396 (1976), to admit the data on phenylpropanolamine, one of the ingredients in the Nasal Decongestants section of that Proposed Monograph, which data were submitted to FDA recently in connection with the Weight Control ANPR, which also covers phenylpropanolamine at the same dosage level.

Statement of Grounds

The "Nasal Decongestants" portion of the Proposed OTC Cold, Cough, Allergy, Bronchodilator and Antiasthmatic Drug Products ("Cough/Cold") Monograph discusses data on the safety and effectiveness of several ingredients, including phenylpropanolamine and its salts. 41 Fed. Reg. 38,312, 38,400 (1976). The Tentative Final Cough Cold Monograph has not yet issued. Thus the most recent classification of phenylpropanolamine (as Category I, II, or III under the Review) was made in 1976, when it was placed in Category I by the Panel. Since then numerous other — and more recent — data on the ingredient have been submitted to FDA in connection with the agency's Advance Notice of Proposed Rulemaking on Weight Control Products for Over-the-Counter Human Use [47 Fed. Reg. 8,466 (1982)]. Phenylpropanolamine is used in such products at the same dosage levels as in nasal decongestants. It was placed in Category I for use in weight control products by the Panel.

In order for FDA to base its decisions concerning the safety and effectiveness of phenylpropanolamine as a nasal decongestant on all of the readily available data, The Proprietary Association urges that the agency reopen the administrative record for Nasal Decongestants to include the more recent data that were submitted on phenypropanolamine in connection with the Weight Control ANPR.

Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

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